BUREAU OF CANNABIS CONTROL
CALIFORNIA

SUMMARY OF PUBLIC COMMENT REGARDING MEDICAL CANNABIS REGULATION AND SAFETY ACT TESTING LABORATORIES PROPOSED REGULATIONS

Earlier this spring, the Department of Consumer Affairs' Bureau of Cannabis Control (Bureau), the Department of Food and Agriculture, and the Department of Public Health released draft regulations for the Medical Cannabis Regulation and Safety Act of 2015. These licensing authorities held several public hearings to accept verbal and written comments regarding the draft regulations. The licensing authorities had planned to move forward with a separate draft regulatory package for the implementation of Proposition 64: The Adult Use of Marijuana Act of 2016. However, in late June, the Legislature passed and the Governor signed into law the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA, also known as Senate Bill 94), which created one regulatory system for both medicinal and adult-use cannabis. As a result, the licensing authorities will withdraw the proposed medical cannabis regulations noticed for public comment on April 28, 2017, and May 5, 2017.

The three cannabis licensing authorities are in the process of drafting emergency regulations based on the new law for the commercial medicinal and adult-use cannabis industries. The licensing authorities will consider the public comments received on the draft medical cannabis regulations and use the feedback to inform the draft emergency regulations. The emergency regulations are expected to be published in November 2017.

This document is intended to provide stakeholders with a high-level summary of the comments received on the proposed medical cannabis regulations published in April and May 2017 and an initial response to those comments by the Bureau. The Bureau appreciates the thoughtful and timely responses made by stakeholders. Please note this is not a comprehensive list of regulation topics. The Bureau will consider every comment received in a continued effort to create effective and reasonable regulations for medicinal and adult-use cannabis activity.

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5237 – DEFINITIONS	
The Bureau received several comments related to the additional definitions applicable only to testing laboratories.	*The Bureau developed these definitions based on the Medical Cannabis Regulation and Safety Act (MCRSA), which has been repealed. The Bureau is evaluating whether changes should be made to the definitions based on the new law, the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) and the public comment.*
MCRSA PROPOSED REGULATIONS § 5238 – APPLICATION	
The ISO/IEC 17025 accreditation requirement for testing laboratories should be removed.	*Business and Professions Code section 26100 requires a testing laboratory to have an ISO/IEC 17025 accreditation. The Bureau does not have the authority to change any requirements contained in the law.*
MCRSA PROPOSED REGULATIONS § 5244 – PROVISIONAL TESTING LABORATORY LICENSE	
The Bureau should not grant a provisional license or accept an application from a testing laboratory that is "in the process of applying" for ISO/IEC 17025 accreditation.	*To ensure that cannabis and cannabis products are available while laboratories are coming into compliance with the new requirements, provisional licenses are needed due to the length of time accreditation takes.*
MCRSA PROPOSED REGULATIONS § 5250 – SAMPLING REQUIREMENTS	
In order to save on cost, the samplers from the testing lab should be able to transport the samples themselves (without the use of a transporter or a transporter license).	*This regulation was based on MCRSA. The current law under Business and Professions Code section 26104 requires testing laboratory staff to transport the sample to the laboratory.*
MCRSA PROPOSED REGULATIONS § 5262 – STORAGE & HANDLING OF SAMPLES	
The requirement that the sample shall be kept on ice in an ice chest, with a physical separation between the ice and the sample, and the temperature shall be maintained at 0 to 6 degrees Celsius may not be beneficial for all cannabis sample types. Refrigeration to the point of freezing has varying effects on plant and plant-based products. The most obvious being the effect of condensation and moisture leading to raised moisture content (added weight can impact various tests), the separation of trichomes from the plant, and the potential for mold growth.	*The Bureau is evaluating this matter and whether samples should be transported and stored based on the manufacturer label or based on how the product is sold at retail.*

SUMMARY OF PUBLIC COMMENT REGARDING MEDICAL CANNABIS REGULATION AND SAFETY ACT TESTING LABORATORIES PROPOSED REGULATIONS

PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5268 – SAMPLING UNPACKAGED HARVEST BATCHES	
The distributor should be the one to sample. The proposed regulations will increase the amount of cost significantly.	*Business and Professions Code section 26104 requires that the sample be taken by a testing laboratory employee. The Bureau does not have the authority to change any requirements contained in the law.*
MCRSA PROPOSED REGULATIONS § 5271 – UNPACKAGED HARVEST BATCH SAMPLE SIZE	
The 0.5 percent minimum sample to be collected should be reduced. For a 9.01 to 10.0-pound harvest batch, 0.5 percent or 22.7 grams of sample to be collected seems excessive. This should be reduced to minimize the amount of waste from the remaining untested harvest batch sample. The laboratory would be responsible for this unnecessary and costly waste disposal.	*The Bureau initially determined that 0.5 percent is the bare-minimum sample amount needed to allow for statistical analysis and to collect a representative sample. The Bureau is currently evaluating whether that size can be reduced while still allowing for a scientifically valid testing process.*
The increments listed in the table are the amounts required to collect for the primary sample and the duplicate sample. The Bureau should not require an additional field duplicate sample because total sample amount will be 1.0 percent of the batch size.	*The Bureau is evaluating whether a duplicate sample should be required and, if so, the size of that sample.*
MCRSA PROPOSED REGULATIONS § 5280 – SAMPLE INCREMENTS FOR PACKAGED CANNABIS GOODS	
The proposed sample increments presented in the table are not proportional. It may also be best to add a separate table or column specifically for concentrates/extracts.	*The Bureau is evaluating whether a separate table would be appropriate to include in the regulations.*
MCRSA PROPOSED REGULATIONS § 5283 – HOMOGENEITY TESTS FOR EDIBLE CANNABIS PRODUCTS	
Ten increments of manufactured edible samples for the homogeneity test, plus the primary samples and the duplicate samples, is excessive and an unreasonable burden. The Bureau should consider reducing the amount of sample mandated for testing.	*The Bureau is currently evaluating the requirements for homogeneity testing.*
The Bureau should test for both CBD and THC, not just one or the other. Also, the Bureau should consider allowing whatever cannabinoid found to be higher than 0.5 mg to be tested for homogeneity. Do not limit this to just THC or CBD, different cannabinoids have different effects.	*Business and Professions Code section 26100 requires the certificate of analysis to include both CBD and THC. The Bureau is considering what other cannabinoids will be tested for.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5286 – CHAIN-OF-CUSTODY PROTOCOL	
The proposed chain-of-custody protocol is not tailored to digital methods. Digital record keeping should be allowed.	*The Bureau plans to allow digital record keeping and is considering what the criteria should be for digital record keeping.*
Assigning a unique increment ID to each increment is not practical, especially if the samples will end up being combined.	*The Bureau is evaluating at what point the increment ID should apply during the testing process.*
MCRSA PROPOSED REGULATIONS § 5289 – SAMPLE REJECTION	
The Bureau's proposed regulation requires the sample be rejected if there is "evidence that the sample was not collected in the manner required by this chapter or the laboratory's sampling standard operating procedures." If the samples must be destroyed because of the reason above, the testing laboratory should bear the burden of the cost of samples that must be recollected.	*The Bureau has determined that the cost of resampling the batch after a sample has been rejected due to how the sample was taken is best left for the parties to negotiate among themselves as with any other commercial industry.*
MCRSA PROPOSED REGULATIONS § 5292 – STANDARD OPERATING PROCEDURES FOR LABORATORY PROCESSES	
A laboratory should make the standard operating procedures accessible to the Bureau upon request and to any local jurisdiction in which the lab holds a local license, permit, or other authorization.	*A laboratory must submit operating procedures to the Bureau. The Bureau will share information with other jurisdictions in a manner consistent with law.*
MCRSA PROPOSED REGULATIONS § 5298 – TESTING METHODOLOGIES	
Methods developed by the laboratories are proprietary. Laboratories' proprietary methodologies need to be protected from competitors in the industry. Recommend adding "where it will be kept in confidentiality" in the end of section 5298(4) text.	*The Bureau will share information in its possession in a manner consistent with law.*
MCRSA PROPOSED REGULATIONS § 5301 – VALIDATION OF NON-STANDARD TEST METHODS & MODIFIED STANDARD TEST METHODS	
The Bureau should allow labs to create their own in-house reference material and potentially provide this to other testing laboratories.	*The Bureau is reviewing this issue further.*

SUMMARY OF PUBLIC COMMENT REGARDING MEDICAL CANNABIS REGULATION AND SAFETY ACT TESTING LABORATORIES PROPOSED REGULATIONS

PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5304 – REQUIRED ANALYSES	
With all of the cannabis testing requirements, the testing laboratories should be able to subcontract out some analyses.	*The Bureau is evaluating whether testing laboratories should be able to subcontract with other licensed testing laboratories to perform some of the required tests.*
MCRSA PROPOSED REGULATIONS § 5307 – CANNABINOIDS	
Using "dry-weight" will overstate the cannabinoid concentrations that appear on the product labels and will be misleading to the consumer.	*Due to the variability of moisture content, dry-weight based concentrations will allow for the uniformity of reporting cannabinoids across the state; therefore, consumers can compare the potency of different batches and strains.*
The only cannabinoids that should only be tested for are those listed on the label.	*The cannabinoids required for testing are either mandated in Business and Professions Code section 26100 or are the most common found in cannabis.*
MCRSA PROPOSED REGULATIONS § 5310 – RESIDUAL SOLVENTS & PROCESSING CHEMICALS	
Analyzing for residual solvents in finished goods, especially edibles, is extremely unlikely to result in any failures if solvents have not been introduced beyond the production stage for the cannabis extract ingredient. The source material for infused products should be tested for residual solvents, rather than the resulting infused products.	*Business and Professions Code section 26100 requires all cannabis and cannabis products be tested in the final form in which it will be consumed or used. The Bureau does not have the authority to change any requirements contained in the law.*
Naphtha and petroleum ether seem unlikely to be present in manufactured products. Also, these are not single compounds but rather mixtures of individual compounds and yield multiple, frequently unresolved peaks when analyzed. The Bureau should reassess to determine if the presence of naphtha and petroleum ether on the list are necessary.	*The Bureau is evaluating whether naphtha and petroleum ether should remain on the list of substances separately tested for.*
The proposed regulations do not include isobutane (CAS 75-28-5). Isobutane is commonly found along with butane and is not uncommon to see in products that use Butane Honey Oil (BHO) extractions. Its toxicity is similar to butane. Isobutane should be added to the list of residual solvents mandated for testing.	*The Bureau is evaluating whether isobutane should be included in testing.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5310 – RESIDUAL SOLVENTS & PROCESSING CHEMICALS *(CONT.)*	
Clarification is needed on what the definition of parts per million (ppm) is in these regulations for both inhalation and non-inhalation intake methods. The ppm unit for inhalation products is volume-based (ppmv) and the ppm units for all other products is weight-based (ppmw). To avoid any confusion, these units should be unified to the weight-based ppmw form, because all residual solvents will be tested in the solid, semi-solid, and liquid forms of products, not the gas form.	*The Bureau is evaluating changing the ppm action levels to weight-based for all cannabis and cannabis products.*
MCRSA PROPOSED REGULATIONS § 5313 – RESIDUAL PESTICIDES	
Proposed pesticide action levels are too low. The limits are reaching the limit of analytical capability with current technology. To detect such levels, a testing laboratory must purchase new, higher-end equipment that would have the capability to detect the proposed 10 parts per billion levels. This will be cost prohibitive, especially for the smaller testing laboratories.	*The Bureau and the Department of Pesticide Regulation are evaluating whether these levels should be adjusted.*
Too many pesticides are required for testing. The Bureau should consider reducing the number of pesticides mandated for testing. It is recommended to use the list of pesticides from AHP (Revision 2014) or Oregon.	*The Bureau and the Department of Pesticide Regulation are evaluating whether the Oregon standards should be used for some of the pesticides required for testing.*
The Bureau should adopt a "zero-tolerance" policy in regard to pesticide use as Colorado has done. After three years the growers in Colorado are responding well and practices have changed. The industry should go organic.	*The Bureau and the Department of Pesticide Regulation are evaluating whether the pesticide levels should be adjusted.*
Assumptions made in the ISOR state that individuals consume 10 percent of their body weight in edibles each day, but this contradicts section 5328 (Heavy Metals) that people ingest 10 grams a day.	*The Bureau and the Department of Pesticide Regulation are evaluating this issue further.*
Setting safety limits based on tobacco standards should not be used as a model for the cannabis industry.	*The Bureau and the Department of Pesticide Regulation are evaluating this issue further.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5313 – RESIDUAL PESTICIDES *(CONT.)*	
A column should be added to the table that specifies the Chemical Abstracts Service numbers for all pesticides. Also, it is unclear if certain pesticides are to be measured as a cumulative residue of cis- and trans- (i.e., cis- and trans-permethrin isomers). Clarification is needed.	*The Bureau and the Department of Pesticide Regulation are evaluating this issue further.*
MCRSA PROPOSED REGULATIONS § 5316 – MICROBIOLOGICAL IMPURITIES	
The Bureau should allow testing labs to use aerobic plate count methods to measure bacterial load on any given sample.	*The Bureau is evaluating this issue further.*
The Bureau should ensure that whatever platform laboratories will be using to detect microbes, they use a method that has been validated specifically for use on cannabis.	*If the laboratory is ISO/IEC 17025 accredited for all microbiological impurities mandated for testing under these regulations, then the accreditation should include approval of their testing methodologies, including testing specific matrices.*
MCRSA PROPOSED REGULATIONS § 5319 – MYCOTOXINS	
Mycotoxins are unlikely to be a problem in this industry. This type of testing should be removed.	*The Bureau is evaluating this issue further.*
The allowable moisture content should be raised to 15 percent. Most common methods used in pharmaceutical companies (i.e., Karl-Fischer method) have not been validated on cannabis. These methods also seem to overestimate water content.	*The Bureau is evaluating this issue further.*
This section is not clear enough. The required water activity testing should be eliminated on manufactured products like concentrates, extracts, and live resin.	*The Bureau is evaluating this issue further and will clarify what type of cannabis products should be tested for moisture content and water activity.*
MCRSA PROPOSED REGULATIONS § 5325 – FILTH & FOREIGN MATERIAL	
This section is not clearly written.	*The Bureau intends to clarify the regulatory language related to filth and foreign material.*
MCRSA PROPOSED REGULATIONS § 5328 – HEAVY METALS	
The Bureau should conduct a study to see if metals testing is really needed. Other states do not see testing failures due to heavy metals and to mandate this testing would be costly to the laboratories and increase turnaround time.	*The Bureau is evaluating if the testing of heavy metals is in fact necessary and, if so, how should it be conducted.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5328 – HEAVY METALS *(CONT.)*	
Action levels are too low. The Bureau should adopt the USP levels in chapter <233> elemental contaminates for edibles.	*The Bureau is evaluating this issue further.*
It is not necessary to require edibles be tested for heavy metals since the raw materials would have already been tested. Also, if most of the metal contamination would be coming from soil, water, or plant nutrients, then the Bureau should mandate testing of those materials.	*Business and Professions Code section 26100 requires that cannabis goods are tested in the final form in which the cannabis goods will be consumed or used.*
Anything imported from outside of the United States should require heavy metals testing, but products produced in the United States should not be tested for metals.	*All cannabis and manufactured cannabis products must be produced in California. Business and Professions Code section 26080 prohibits the transportation or distribution of cannabis goods outside of the state, unless allowed by federal law.*
MCRSA PROPOSED REGULATIONS § 5331 – TERPENES	
Since the terpenes are generally present in products at a much lower concentration than cannabinoids, using mg/g may be a more appropriate unit of measurement to report, rather than percent.	*The Bureau is evaluating this requirement and is considering making changes based on the type of product.*
MCRSA PROPOSED REGULATIONS § 5334 – CERTIFICATE OF ANALYSIS	
The moisture content requirement should be removed from the certificate of analysis.	*The Bureau is evaluating the moisture content requirement and will have the certificate of analysis be consistent with that requirement.*
Failure to provide timely and accurate data is grounds for discipline—define what timely and accurate mean. Define what is the disciplinary action that would be taken.	*The Bureau's enforcement and disciplinary guidelines are currently in development.*
The requirement for a testing laboratory to report a sample containing synthetic cannabinoids as "failed" should be removed. Detecting synthetic cannabinoids requires unique methods and quality control, and possibly additional ISO/IEC 17025 method scope accreditation in order to report synthetic cannabinoid results.	*The Bureau is evaluating whether this requirement should be removed.*
The requirement to report "within 24 hours" may not be feasible if the next day is the weekend (laboratories are generally not open on weekends) or if the next day is a holiday.	*The Bureau intends to amend the requirement to allow an expanded time frame to report results.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5340 – NO RETESTING WITHOUT REMEDIATION	
The remediation plan should be approved by the Bureau prior to the remediation, thus the Bureau will be authorizing the retesting of the product. The Bureau should be provided the remediation document, not the testing laboratory.	*The Bureau requires that any product that has been remediated will have to be retested. The Bureau is evaluating whether the remediation documentation should be attached to the certificate of analysis.*
The Bureau should allow products that fail and can't be remediated to be donated to compassion programs.	*If a product fails laboratory testing, this deems it unsafe for the consumer.*
MCRSA PROPOSED REGULATIONS § 5349 – QUALITY-CONTROL ELEMENTS	
The Bureau should allow testing laboratories to set up some standard quality control (QC) samples that will be used in validation to ease the amount of QC samples that need to be conducted with every analytical batch.	*Quality control samples are used to measure accuracy, precision, contamination, and matrix effects, and this should be accounted for in every analytical batch.*
MCRSA PROPOSED REGULATIONS § 5352 – LIMITS-OF-DETECTION & LIMITS-OF-QUANTITATION CALCULATIONS FOR QUANTITATIVE ANALYSES	
The requirement for the limit of detection for chemical methods to be less than one-tenth of the action level for each analyte should be removed because this level of quantification is not possible for some pesticides with 0.01 ppm action levels.	*The Bureau and the Department of Pesticide Regulation are evaluating this requirement.*
MCRSA PROPOSED REGULATIONS § 5355 – DATA PACKAGE	
There should be some flexibility as to who can verify and approve data packages.	*The Bureau is considering allowing persons, other than the laboratory director, in supervisory or management positions to review, verify, and approve data packages.*
MCRSA PROPOSED REGULATIONS § 5358 THROUGH § 5364 – PROFICIENCY TESTING	
Requirements to pass proficiency testing should vary depending on the test being performed. Proficiency testing should be flexible as consistent testing methods for cannabis are not fully developed. Testing laboratories should be allowed to develop, implement, and sell proficiency tests to other labs.	*Successful participation in proficiency testing will demonstrate the laboratory's competence and help sustain ISO/IEC 17025 accreditation, which is mandated by Business and Professions Code section 26100. The Bureau is evaluating whether additional provisions should be included in the regulations regarding proficiency testing, including provision of tests from one laboratory to another.*

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PUBLIC COMMENT	BUREAU RESPONSE
MCRSA PROPOSED REGULATIONS § 5373 – PERSONNEL QUALIFICATIONS	
Laboratory personnel education and experience requirements need to be more flexible.	*The Bureau is evaluating whether these requirements should be modified.*
The requirement for all personnel listed to have "practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body" is not defined and is not realistic. It will disqualify many highly talented candidates.	*The Bureau is evaluating whether these requirements should be modified.*
Students and interns should be allowed to work in labs to perform basic tasks.	*Students and interns are not prohibited from working in laboratories, but must meet the minimum requirements to perform specific tasks as required by the law and regulations.*
This section should clearly state that a testing laboratory shall not hire an employee or volunteer, if the person works or volunteers for another licensee engaging in commercial cannabis activity unless the other medical cannabis licensee is a testing laboratory.	*Business and Professions Code section 26053 prohibits a testing laboratory from employing any person also employed by a commercial cannabis licensee that is not a testing laboratory.*
MCRSA PROPOSED REGULATIONS § 5400 – ELECTRONIC DATA	
There should be an option to store this information in a cloud-based system or using a cloud-based service.	*The Bureau is evaluating additional options for electronic storage of data, including cloud-based storage.*
OTHER COMMENTS	
Testing every batch is too burdensome and will create substantial additional costs.	*Business and Professions Code section 26100 now allows the Bureau to determine which batches will be tested. The Bureau is evaluating the criteria for batch testing.*
Products should be tested during the specified grace period but there should be no official "pass or fail" determination. This would help ease into the testing regulations. The Bureau should also consider phased-in testing so the labs can start testing for the majority of contaminates, then add pesticides and metals.	*The Bureau is evaluating this further.*

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PUBLIC COMMENT	BUREAU RESPONSE
OTHER COMMENTS *(CONT.)*	
If a single manufactured batch is sent to multiple distributors, each distributor is required to independently test their batch prior to retail sale, which seems inefficient. Allowing manufacturers to send samples directly to testing laboratories would resolve this problem.	*Business and Professions Code section 26110 requires the distributor to arrange for testing and store products during the testing period. The Bureau does not have the authority to change any requirements contained in the law. A manufacturer can choose to send its batch to one or multiple distributors.*
The state should implement some type of surveillance program, where products that have been tested are randomly pulled from the shelf and tested for all the tests or even just a simple potency test would be sufficient to check results.	*The Bureau will be conducting inspections and other enforcement activities to ensure that licensees are in compliance with the laws and regulations applicable to commercial cannabis activity.*
Industry or regulators should develop a public education campaign to educate first-time cannabis users.	*Business and Professions Code section 26211 requires the Department of Health Care Services to develop a public information program. In addition to other topics, the program will address the dangers of impaired driving, the potential harm of overuse of cannabis goods, and the potential harm of using cannabis goods while pregnant or breastfeeding.*